



STATE OF CALIFORNIA

## STATE BOARD OF EQUALIZATION

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May 15, 2015

VIA INTERNET

Dear Interested Party:

The Audit Manual (AM) is a guide for the Board of Equalization (BOE) staff in administering tax and fee programs. It is available to the public and can be accessed from the BOE web page at <http://www.boe.ca.gov/sutax/staxmanuals.htm>.

The Sales and Use Tax Department (SUTD) is proposing to revise AM Chapter 4, *General Audit Procedures*. Section 0418.00, *Audit of Prescription Medicines*, is being revised to provide guidance to staff on the application of Regulation 1591, *Medicines and Medical Devices*, when defining “medicines.” The revision is based on direction from the Business Taxes Committee (BTC) at the November 2014 BTC meeting.

The revision material is provided on the following pages for the convenience of interested parties who may wish to submit comments or suggestions. Please feel free to publish this information on your website or otherwise distribute it to your association/members.

If you have any comments or suggestions related to the proposed AM revisions, you may contact the BOE at [AM.RevisionSuggestions@boe.ca.gov](mailto:AM.RevisionSuggestions@boe.ca.gov). Your comments or suggestions must be received by BOE no later than **July 17, 2015**, in order to be considered by staff. Thank you for your consideration.

Sincerely,

Susanne Buehler, Chief  
Tax Policy Division  
Sales and Use Tax Department

## AUDIT OF PRESCRIPTION MEDICINES

0418.00

### GENERAL

0418.05

Revenue and Taxation Code (RTC) section 6369 exempts the sale or use of defined medicines, under certain conditions, and is interpreted and implemented in Regulation 1591, *Medicines and Medical Devices*. In order for a medical product to meet the definition of medicine, it must be determined whether the product functions as a medicine as provided in the statute. RTC sections 6369.1, 6369.2, 6369.4 and 6369.5 provide exemptions for certain items which might otherwise be taxable. Regulations implementing these statutes are listed in section 0418.15.

Medicines sold under a prescription issued by a physician, dentist, surgeon, or podiatrist for the treatment of a human being, and filled by a registered pharmacist, are exempt from the sales tax. ~~In addition, effective January 1, 1995, tax also~~ does not apply to medicine furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, ~~or health facility, or to certain political entities~~ for the treatment of a human being, or to an institution of higher education for instruction or research. For complete definitions of terminology, and other conditions under which medicines are exempt, see the applicable sections of the law, rules and regulations. ~~From an audit standpoint, exempt sales to and by doctors, dentists, hospitals and certain political entities present no particular problem. The following section is limited to auditing prescription pharmacies.~~

### DEFINITIONS

0418.10

RTC section 6369 (b), as interpreted by Regulation 1591 (hereafter referred to as 1591) subdivision (a)(9), defines “medicines” to mean and include “any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment, or prevention of disease and which is commonly recognized as a substance or preparation intended for that use.” 1591 subdivision (a)(9)(A) further states that “medicine” means, “except where taxable for all uses as provided in subdivision (c), any product fully implanted or injected in the human body, or any drug or any biologic, when such are approved by the U.S. Food and Drug Administration to diagnose, cure, mitigate, treat or prevent any disease, illness or medical condition regardless of ultimate use.”

RTC section 6369 (b), as interpreted by 1591 subdivision (c)(2), excludes “articles which are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices, or other mechanical, electronic, optical or physical equipment or articles or the component parts and accessories thereof.” Therefore, medical devices generally do not meet the definition of “medicines.”

However, 1591 subdivision (b) provides separate and distinct definitions of the term “medicines” that apply independently to the sale of certain medical devices. This means that a medical device which might generally be excluded from the definition of “medicines” may qualify under subdivision (b), like breast tissue markers or neck collars. Also, a substance, drug, or device may have multiple uses, like Botox or breast implants. If one of the uses qualifies the item as a medicine, the item is considered a medicine for all uses.

## **AUDITING PROCEDURES**

**0418.1015**

The application of tax to sales of medical products can be complicated. Due to rapid technological advancements in the field of medicine, it is important that the auditor ensure proper application of the laws, rules, and regulations pertaining to medicines. When determining if a medical product meets the definition of a medicine, an auditor should review whether the product functions as a medicine pursuant to RTC section 6369 and Regulation 1591.

In applying the regulation to audit situations, the auditor must recognize that the provisions in Regulation 1591 subdivisions (a), (b), and (c) are interrelated, and all three must be considered when determining if a particular product meets the definition of a medicine. The definition of medicines may cause confusion during an audit. Therefore, the auditor should review subdivision (a)(9) for general definitions, then subdivision (c) which specifically excludes certain items from the definition of medicines. Finally, the auditor should refer to subdivision (b) which provides that certain items which might otherwise be excluded are defined as “medicines.” A product excluded from the definition of “medicines” for all uses under subdivision (c) is also excluded from “medicines” under subdivision (a), unless it satisfies at least one of the listed conditions provided in subdivision (b).

For example, a device is generally excluded from the definition of “medicines” in subdivision (c). As such, a device would not be considered a medicine under the general definition provided in subdivision (a), unless it meets the conditions specified in subdivision (b). For example, if the device is designed to be worn on or in the patient to replace or assist the functioning of a natural part of the human body, it would be considered a prosthetic device and is a medicine under subdivision (b)(5). A device that is not worn on or in the patient, or is worn for a purpose other than to replace or assist the functioning of a natural part of the human body, would not be a prosthetic device and would therefore not meet the statutory definition of “medicines.”

Certain items which might otherwise be taxable under Regulation 1591 may have particular statutory exemptions. When appropriate, the auditor should also refer to the following regulations:

- 1591.1 Specific Medical Devices, Appliances, and Related Supplies
- 1591.2 Wheelchairs, Crutches, Canes, and Walkers
- 1591.3 Vehicles for Physically Handicapped Persons
- 1591.4 Medical Oxygen Delivery Systems

## **CONSIDERATION OF FUNCTIONALITY**

**0418.20**

There are two aspects of functionality that the auditor should consider when evaluating whether the product qualifies as a medicine. First, the auditor must consider the actual purpose and use of the product, with respect to the definition of “medicines” in RTC 6369. Second, if a device, appliance, or other medical item is essentially a technologically-advanced replacement that is functionally equivalent to an item already defined as a medicine, the product may also qualify as a medicine. As an example, Regulation 1591, subdivision (b)(2) provides that sutures, whether or not permanently implanted, are considered “medicines.” It has been previously

determined that “sutures” means items used to surgically unite two surfaces by means of stitches. Surgical spiral tacks used in hernia repair are a technological advance over sutures. The tacks are implanted into the body and perform the same function of uniting two pieces of skin. Although they are not specifically listed in subdivision (b)(2), surgical tacks qualify as exempt medicines.

The following examples illustrate the steps an auditor should take when determining whether a particular product qualifies as a medicine:

Example 1:

Device X is a product that is implanted in a patient to detect and record abnormal heart rhythms.

- The auditor looks at the general definitions of medicines in Regulation 1591, subdivisions (a)(9)(A) and (a)(9)(B), and finds that Device X appears to meet the general definition of a medicine under subdivision (a)(9)(A), including that it is approved or cleared by the FDA to diagnose and/or prevent disease.
- However, because subdivision (a)(9)(A) begins with the caveat, “except where taxable for all uses as provided in subdivision (c),” the auditor next needs to look at subdivision (c) and finds in subdivision (c)(2) that certain items are excluded from the definition of medicines, including appliances, devices, or other mechanical or electronic equipment. Device X now appears to be *excluded* from the definition of a medicine.
- Subdivision (c) directs the auditor to review subdivision (b) which provides *exceptions* to the exclusions. The auditor sees there is an exception for devices that are “permanently implanted articles.” Although Device X is implanted, it does not “assist the functioning of... any natural organ, artery, vein, or limb” as required by subdivision (b)(2). Device X does not qualify as a medicine under subdivision (b)(2) and is excluded for all uses under subdivision (c) and its sale is subject to tax.

Example 2:

Device Z is a product that is implanted in a patient to correct abnormal heart rhythms.

- The auditor looks at the general definitions of medicines in Regulation 1591, subdivisions (a)(9)(A) and (a)(9)(B), and finds that Device Z appears to meet the general definition of a medicine under subdivision (a)(9)(A), including that it is approved or cleared by the FDA to diagnose and/or prevent disease.
- However, as in Example 1, the auditor next needs to look at subdivision (c) and finds in subdivision (c)(2) that certain items are excluded from the definition of medicines including appliances, devices, or other mechanical or electronic equipment. Device Z now appears to be *excluded* from the definition of a medicine.
- Lastly, upon review of subdivision (b), the auditor sees that subdivision (b)(2) contains an exception for devices that are “permanently implanted articles” and “assist the functioning of...any natural organ, artery, vein, or limb.” Device Z is implanted in the patient and, unlike Device X, which passively detects and records heart rhythms, it provides defibrillation energy to correct abnormal heart rhythms when detected. In other words, Device Z does “assist the functioning of... [a] natural organ,” the heart, as required by subdivision (b)(2) and qualifies as a medicine.

### Example 3:

Device Y is a device that is approved by the FDA to be implanted in the body either for cosmetic reasons or to replace a body part after it has been surgically removed (i.e. post-surgically). For the audit in question, it is solely being used for cosmetic reasons.

- The auditor looks at the general definitions of a medicine in Regulation 1591, subdivisions (a)(9)(A) and (a)(9)(B), and finds that Device Y appears to meet the general definition of a medicine under subdivision (a)(9)(A).
- The auditor next looks at subdivision (c) and finds in subdivision (c)(2) that certain items are excluded from the definition of medicines, including appliances, devices, or other mechanical or electronic equipment. Device Y now appears to be *excluded* from the definition of a medicine.
- Lastly, upon review of subdivision (b), the auditor sees that subdivision (b)(5) contains an exception for prosthetic devices that are designed to be worn on or in the patient to “replace or assist the functioning of a natural part of the human body.” Device Y does not meet that definition when being used for a cosmetic purpose, but regardless of its cosmetic use here, it is approved by the FDA to help cure and/or mitigate a medical condition when used post-surgically. The fact that it qualifies as a medicine under subdivision (b)(5) when used post-surgically, even though it is not being used for that purpose in this instance, means that it is not excluded **for all uses** under subdivision (c), and therefore qualifies as a medicine under subdivision (a)(9)(A).

## **PRESCRIPTION PHARMACIES**

**0418.25**

Section 4331 of the Business and Professions Code requires that all prescriptions filled shall be kept on file and open for inspection by duly constituted authorities. Also, Regulation 1591 requires that “any deduction on account of sales of medicines shall be supported by appropriate records.” The only records specifically required by regulation are the prescriptions themselves, which must be numbered and filed in numerical sequence. Refills are required to be noted on the reverse side of the prescription or on a separate attachment thereto, with the date of refilling and initialed by the pharmacist.

Many pharmacies keep a “prescription register” to record the prescription number, prescriber’s name, patient’s name, date sold, and the sales price of the prescription. When pharmacies use this “register” as a basis for their deduction the auditor need only apply normal verification techniques to determine the accuracy of the claimed deduction. Where such a “register” is not kept, the auditor should first determine taxpayer’s method of compiling the deduction and apply appropriate testing techniques to verify the accuracy of the detail supporting the compilation of the deduction. The auditor should be mindful of the requirement in Regulation 1591 that the taxpayer must support the claimed deduction by appropriate records.